

K021882

JUL 11 2002

## 510(k) SUMMARY

### Safety and Effectiveness

“This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.”

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#### CRPex-HS CRP Calibrator Set

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##### Submitter

Name, Good Biotech Corp.  
Address, 38 34<sup>th</sup> Road Taichung Industrial Park Taichung City 407 Taiwan  
R.O.C.  
Telephone number, +886-4-23596873  
Contact person, Victor Chiou  
Preparation date June 5, 2002

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##### Device

Trade name, CRPex-HS CRP Calibrator Set  
Common name, CRP Calibrators  
Classification name C-reactive protein immunological test system (21CFR 866.5270)

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##### Predicate Device

Trade name, Wako CRP-UL Calibrator Set  
510(k) number K003342

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##### Description / Intended Use

The calibrators contain certain quantities of human C-reactive protein (CRP). CRPex-HS CRP Calibrator Set is intended to be used with CRPex-HS C-Reactive Protein LIT Assay for the quantitative determination of CRP in serum samples.

The measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

For *in vitro* diagnostic use.

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### Substantial Equivalence

Item\Device	CRPex-HS CRP Calibrator Set	Wako CRP-UL Calibrator Set
Matrix / Biological Sources	Liquid human serum	Liquid human serum
Preparation	Ready for use	Ready for use
Expected CRP Concentration (mg/L)	0.00	0.00
	0.50	1.25
	1.50	2.50
	5.00	5.00
	10.00	9.00
	20.00	
Traceability	CAP/BCR/IFCC RPPHS, lot 91/0619	CAP/BCR/IFCC RPPHS, lot 91/0619

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### Correlation

$$y = 1.045 x - 0.141$$

x = Wako CRP-UL

y = CRPex-BR CRP LIT Kit

$$R^2 = 0.998$$

N = 67

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### Conclusion

Good Biotech Corp.'s CRPex-BR CRP Calibrator Set is substantially equivalent to the predicate device Wako CRP-UL calibrator set.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JUL 11 2002**

Mr. Victor Chiou  
President  
Good Biotech Corporation  
38 34th Road  
Taichung Industrial Park  
Taichung City, Taiwan R.O.C.

Re: k021882  
Trade/Device Name: CRPex-HS CRP Calibrator Set  
Regulation Number: 21 CFR 866.5270  
Regulation Name: C-reactive Protein Immunological Test System  
Regulatory Class: Class II  
Product Code: DCN  
Dated: June 5, 2002  
Received: June 7, 2002

Dear Mr. Chiou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

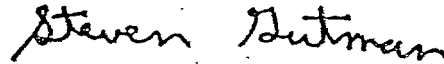
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 021882

Device Name: CRPex-HS CRP Calibrator Set

### Indications For Use:

Good Biotech Corp. CRPex-HS CRP Calibrator Set is intended to be used with CRPex-HS C-Reactive Protein LIT Assay for the quantitative determination of C-reactive protein (CRP) in serum samples.

*For In Vitro Diagnostic Use.*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

### Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109) (Optional Format 1-2-96)

J. P. Reeves for S. Altair  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K021882